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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,298	06/20/2003	Julian N. Nikolchev	016355-002580US	6671

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EXAMINER
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BROWN, MICHAEL A

ART UNIT	PAPER NUMBER
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3772

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/600,298	<b>Applicant(s)</b> NIKOLCHEV ET AL.	
	<b>Examiner</b> MICHAEL BROWN	<b>Art Unit</b> 3772	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-19,35,36,106 and 107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-19,35,36,106 and 107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-3-09</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-18 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Phelps '259.

As for claims 12 and 35 Phelps discloses in figure 5 a vasoocclusion coil that anticipates a contraceptive or sterilization device for occluding a lumen (capable of being a reproductive lumen) and (capable of preventing the passage of reproduction cells therethrough), comprising a tubular member 136, having a first end 138, a second end 140, a lumen (the longitudinal opening inside of 136), extending therein, which is at least in part expandable (from a linear fashion when introduced into a catheter to a pre-selected shape, col. 3, lines 25-31, once removed from the catheter, the tubular member is made of a shape memory material (Nitinol), which allows it to expand from a smaller configuration to a larger configuration), within the reproductive body lumen, a mesh 130, connected to the tubular member (col. 2, lines 62-64), which is permeable (having opening inside of the mesh), for allowing tissue ingrowth (col. 1, lines 49-52).

As for claims 13 and 36, Phelps discloses in figure 5 a vasoocclusion coil that anticipates a contraceptive device installed within a lumen (that is capable of being a lumen in a patient's reproduction system), comprising a tubular member 136, having a

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first end 138, a second end 140, a lumen (the longitudinal opening inside of 136, fig. 5), extending therein, having a portion thereof which is secured to a body wall (the lumen of the tubular member is secured to the body wall portion in order to occlude the lumen within the body once the tubular member assumes its pre-selected shape), an occluding member 130, connected to the tubular member (col. 2, lines 62-64), comprising an epithelialized mesh (the mesh 130 is an epithelialized mesh because it permits tissue ingrowth into the tubular member), which occludes the lumen (col. 4, lines 6-11), of the patient's (capable of being a reproduction system) sufficiently to prevent the passage of (capable of being reproductive cells), reproductive cells.

As for claim 14, Phelps discloses in figures 1-4 a vasoocclusion coil that anticipates a contraceptive system, comprising a catheter 100, having a proximal end (the end opposite 104), a distal end 104, a lumen (the opening that 108 extends into), extending at least in part therein, a contraceptive device 136, device releasably connected to the catheter (in order to insert the tubular member and remove the catheter, the tubular member has to be releasably connected thereto), having a tubular member (the tubular member is 136), that has a first end 138 and a second end 140, a lumen (the opening extending along the longitudinal axis of 136), extending therein, which is at least in part expandable (from a linear fashion when introduced in a catheter to a pre-selected shape, col. 3, lines 25-31, the tubular member is made of a shape memory material which allows it to expand from a smaller configuration to a larger configuration) within a lumen (which is capable of being a reproductive body lumen), a mesh 130, connected to the tubular member (col. 2, lines 60-65), which is permeable to

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allow tissue ingrowth (col. 1, lines 50-53), to thereby occlude the lumen (col. 4, lines 6-11).

As for claim 15, Phelps discloses a method of contraceptive (being capable of occluding a lumen) comprising the steps of inserting within a desired lumen a contraceptive device comprising a tubular member 136, and a mesh 130, connected thereto, expanding the tubular member (from a smaller linear configuration to a larger pre-selected configuration), within the body lumen, securing the expanded tubular member to a wall portion defining at least in part the body lumen (col. 4, lines 6-11) and epithelializing the mesh (allowing tissue ingrowth col. 1, lines 50-53), to occlude the body lumen, col. 4, lines 6-11).

As for claim 16, Phelps discloses the method step of expanding the tubular member comprising the step of releasing a radially compressive force (the force is applied to the tubular member to compress it into a linear shape inside the catheter), afterwards the tubular member is released from the catheter and allow to expand to a pre-selected shape.

As for claim 17, Phelps discloses the method wherein the contraceptive device is disposed within the lumen of a delivery catheter (fig. 1), the step of releasing the radially compressive force comprises longitudinally displacing the tubular member out of the distal end of the delivery catheter (fig. 1).

As for claims 18, Phelps discloses the expandable tubular member 136 is disposed within the body lumen for a sufficient time for it to be epithelialized within the body lumen and thereby secured to the wall portion (col. 4, lines 6-11).

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 106-107 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Callister '116.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 19 is rejected under 35 U.S.C. 102(a) as being anticipated by Phelps.

As for claim 19, Phelps discloses a vasocclusion coil that anticipates a contraceptive or sterilization device for occluding (capable of occluding a lumen which can be a fallopian tube) to inhibit conception comprising a tubular structure 136, having

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a first end 138, a second end 140, a lumen (the longitudinal opening extending through 136), extending therein, the tubular structure is capable of expanding in the fallopian tube (to its pre-selected shape), from a first configuration (linear inside of the delivery catheter) to a second larger configuration (a pre-selected shape once it is removed from the catheter) and a tissue ingrowth element 130, connected to the tubular structure, the tissue ingrowth element is capable of inciting tissue ingrowth (col. 1, lines 50-53), to occlude the fallopian tube.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL BROWN whose telephone number is (571)272-4972. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Brown/  
Primary Examiner, Art Unit 3772